REMARKS/ARGUMENTS

I. Status of the Claims

After entry of this amendment, claims 1-4 and 15-17 are pending in this application, with claims 5-14 having been previously withdrawn, claims 1-4 having been amended herein, and new claims 15-17 having been added.

Claim 1 is amended to replace "An adjuvant consisting essentially of" with "A pharmaceutical composition comprising". Support is provided in the specification at, *e.g.*, page 14, lines 16-20. Claim 1 is also amended to delete "comprising" before "a pharmaceutically acceptable carrier".

Claims 2-4 are amended to replace "adjuvant" with "pharmaceutical composition". Support is provided in the specification at, *e.g.*, page 14, lines 16-20.

New claims 15-17 are supported in original claims 1-2 and in the specification at, *e.g.*, page 6, lines 16-21, page 9, lines 29-34, and Examples 6 to 10. Support for "pharmaceutical composition" in new claims 15-16 is provided in the specification at, *e.g.*, page 14, lines 16-20. Support for "consisting essentially of" and "as a sole active ingredient" in new claim 17 is provided in the specification at, *e.g.*, page 1, lines 6-10, and page 7, lines 10-22.

No new matter is added by these amendments and new claims.

II. Claim Rejections

1. Double Patenting

Claims 1-4 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of co-pending Application No. 10/363,484 (the '484 application).

Applicants are filing herewith a terminal disclaimer, which has been signed by an attorney of record in compliance with 37 C.F.R. § 1.321(c). This terminal disclaimer, which disclaims the '484 application, is being filed for the purpose of expediting prosecution and should not be construed as an acquiescence to double patenting.

Applicants respectfully submit that this terminal disclaimer overcomes the provisional rejection of claims 1-4 under the judicially created doctrine of obviousness-type double patenting. Applicants respectfully submit that this terminal disclaimer also overcomes the provisional rejection of new claims 15-17 under the judicially created doctrine of obviousness-type double patenting. Accordingly, Applicants respectfully request that the provisional double patenting rejection of claims 1-4, as well as new claims 15-17, be withdrawn.

2. Anticipation

The rejection of claims 1-3 as allegedly being anticipated by Lederer et al. (*J. Agroc. Food Chem.* 47:4611-4620, 1999) (Lederer) has been maintained. The Examiner cites Lederer as discussing 18 carbon hydroxy unsaturated fatty acids with the trihydroxy-monoene structure recited in claim 3.

The rejection of claims 1-4 as allegedly being anticipated by Hamberg et al. (Plant Physiology, 110:807-815, 1996) (Hamberg) has been maintained. The Examiner cites Hamberg as discussing an 18 carbon hydroxy unsaturated fatty acid with the trihydroxy-monoene structure recited in claim 3, wherein the fatty acid is isolated from *Avena sativa* seed homogenates.

The rejection of claims 1-4 as allegedly being anticipated by Miyaichi et al. (Nature Medicines, 49:24-28, 1005) (Miyaichi) has been maintained. The Examiner cites Miyaichi as discussing an 18 carbon hydroxy unsaturated fatty acid with the trihydroxy-monoene structure recited in claim 3, wherein the fatty acid is isolated from *Sparganii rhizona*.

The rejection of claims 1-3 as allegedly being anticipated by Quinton et al. (Tetrahedron Letters 32:4909-4912, 1001) (Quinton) has been maintained. The Examiner cites

Quinton as discussing 18 carbon hydroxy unsaturated fatty acids with the trihydroxy-monoene structure recited in claim 3.

Applicants respectfully traverse these rejections as they may be applied to claims 1-4 as amended, and to new claims 15-17.

The Examiner alleges that the cited references, Lederer, Hamberg, Miyaichi and Quinton, all disclose the claimed 18-carbon hydroxyl unsaturated fatty acids in combination with water, thereby meeting all the limitations of the claims. Applicants respectfully disagree. In Lederer, the fatty acids are in solvents such as pyridine, DMF and diethyl ether. In Hamberg, the fatty acids are in a solvent such as methanol/chloroform. In Miyaichi, the fatty acids are extracted with methanol. In Quinton, the fatty acids are produced in solvents such as benzoyl chloride, pyridine/dichloromethane, and potassium carbonate in methanol/water. The above solvents disclosed in combination with the 18 carbon hydroxy unsaturated fatty acids are unacceptable for administration to a subject for any medicinal purpose.

In contrast, the claimed 18 carbon hydroxy unsaturated fatty acids are formulated as pharmaceutical compositions. A pharmaceutical composition cannot comprise solvents unacceptable for pharmaceutical use. In each of the cited references, the 18 carbon hydroxy unsaturated fatty acids is present in solutions that are incompatible with pharmaceutical administration to an animal, that is, the disclosed fatty acids are in solutions/solvents/buffers that are not considered to be pharmaceutically acceptable carriers, as recited in amended claim 1. Accordingly, none of the cited references discloses a pharmaceutical composition comprising a purified or synthesized 18 carbon hydroxy unsaturated fatty acid and a pharmaceutically acceptable carrier, as recited in amended claim 1.

Because none of the cited references discloses the currently claimed pharmaceutical composition, Applicants respectfully request that the rejection of claims 1-3 as being anticipated by Lederer and Quinton, and the rejection of claims 1-4 as being anticipated by Hamberg and Miyaichi, be withdrawn.

New claims 15-17 are not anticipated by Lederer, Quinton, Hamberg and Miyaichi for at least the same reasons as claims 1-4. New claim 17 is not anticipated by Miyaichi for an additional reason, namely, Miyaichi fails to disclose the 18 carbon hydroxy unsaturated fatty acid as the sole active ingredient. Miyaichi only discusses the 18 carbon hydroxy unsaturated fatty acid as one of 21 compounds in the rhizome of the herb "Sanleng," and does not disclose that this fatty acid is responsible for Sanleng's therapeutic effects, whereas new claim 17 recites the hydroxy unsaturated fatty acid as the sole active ingredient.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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Attachments
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